Remarks

Rejections under 35 U.S.C. 112

Claims 49 and 50 were rejected under 35 U.S.C. 112 on the basis that claim 48 lacks antecedent basis. The claims have been amended to provide antecedent basis.

Claims 48-51 have been rejected under 35 U.S.C. 112, first paragraph, lack of written description. This rejection is respectfully traversed.

The Legal Standard for Compliance with Written Description

The most recent articulation of the requirement under 35 U.S.C. 112, for written description, was made by the Court of Appeals for the Federal Circuit in its decision in Amgen Inc. v. Hoechst Marion Roussel, Inc and Transkaryotic Therapies, Inc, 314 F3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003).

> "Section 112 of the patent statute describes what must be contained in the patent specification. Among other things, it must contain "a written description of the invention, and of the manner and process of making and using it . . . [such] as to enable any person of ordinary skill in the art to which it pertains . . . to make and use the same . . . ." 35 U.S.C. § 112 ¶ 1. Thus, this statutory language mandates satisfaction of two separate and independent requirements: an applicant must both describe the claimed invention adequately and enable its reproduction and use. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

"The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." Id. at 1561, 19 USPQ2d at 1115 (citation omitted). Satisfaction of this requirement is measured by the understanding of the ordinarily skilled artisan. Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997) ("The description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" Enzo Biochem v. Gen-Probe, Inc., 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002) (citation omitted)."

"Indeed, the district court's reasoned conclusion that the specification's description of producing the claimed EPO in two species of vertebrate or mammalian cells adequately supports claims covering EPO made using the genus vertebrate or mammalian cells, renders Eli Lilly listless in this case. Amgen, 126 F. Supp. 2d at 149, 57 USPQ2d at 1507."

Analysis

Accordingly, the mere fact that there is only an example of two different antibodies

which are conformation and lipid independent having been made to a delipidized and reduced antigen does not mean that applicants are not entitled to broader claims under the written description requirement of 35 U.S.C. 112. Moreover, the application does not describe antibodies only to a single antigen, Apo B-100, but also refers to antibodies to other apolipoproteins including Apo A-I, which are lipid independent. See page 28, lines 1-16.

The issues are whether applicants had conception of (1) the subgenus of solubilization with a reducing or denaturing agent; (2) removal of all self-aggregated and degraded material; (3) soluble lipoprotein as an immunizing material; (4) immunization with an apolipoprotein that is delipidated, reduced, carboxymethylated and solubilized with a reducing or denaturing agent that is free from aggregates and degradation productions and (5) polyclonal antibodies.

The law has long allowed an applicant to claim all that he is entitled to, not forcing him to limit his claims to a specific example, if other means for achieving the same step would be known to those skilled in the art and not require undue experimentation. That is clearly the case here.

Allowance of all claims 48-51, as amended, is earnestly solicited.

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